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REMARKS/ARGUMENTS

The Examiner rejected all Claims 1, 3-11, 14-21, and 25-32 as obvious in view of, among others, Gross, et al., U.S. Patent No. 6,354,991 ("the '991 patent"), issued March 12, 2002 and Schulman, et al., U.S. Patent No. 5,193,540 ("the '540 patent"). Applicants hereby respectfully traverse this rejection because (1) Gross, et al., do not teach inhibitory stimulation as claimed, (2) the Examiner may not use hindsight analysis in relying upon the teachings of Gross, et al., (3) combining the teachings of Gross, et al., with Schulman, et al., would destroy the purpose of the invention of Schulman, et al., and (4) Schulman, et al., teach away from the teachings of Gross, et al. Although not pursued in the present paper, Applicants also reserve the right to establish that the '991 patent does not qualify as a prior art reference under 35 U.S.C. §102 and thus cannot be used to reject the claims of the present application under 35 U.S.C. §103.

First, Gross, et al., do not teach inhibitory stimulation as required by 35 U.S.C. §103. Applicants appreciate the Examiner's admission that Tanagho, et al., U.S. Patent No. 4,703,755 ("the '755 patent"), do not teach "the step of providing an inhibiting pulse to the sacral nerve to control incontinence through an internally placed stimulator." Office Action mailed May 6, 2004, Paper #5, page 2. Yet Applicants disagree that Gross, et al., teach "that it is old and well known to provide continuous electrical stimulation of the sacral nerve to reduce or eliminate urge incontinence." *Id.* Rather, Gross, et al., merely teach that at least as early as the issue date of the '991 patent, an implantable pulse generator could be implanted in the lower abdomen in a major surgical procedure under general anesthesia, and that "[t]he continuous electrical stimulation of the [sacral] nerve has been found to reduce or eliminate urge incontinence in some patients." '991 patent, col. 2, lines 29-44. Yet, urge incontinence may be reduced or eliminated without inhibitory stimulation, as required by Claims 1, 3-11, 14-21, and 25-32, and Gross, et al., fail to teach the reduction or elimination of urge incontinence by use of inhibitory stimulation.

For example, as taught by much of the prior art of record, urge incontinence may be reduced or eliminated through the use of excitatory stimulation at low frequencies

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(e.g., Sawan, U.S. Patent No. 6,393,323, applies stimulation at 15-40 Hz; Boveja, U.S. Patent No. 6,205,359, applies stimulation at 15, 20, 25, or 30 Hz; Lin, U.S. Patent No. 5,833,595, applies stimulation at 20 or 30 Hz; and Najafi, et al., U.S. Patent No. 5,314,458 apply stimulation at up to 40 Hz). Because Gross, et al., fail to teach inhibitory stimulation, but more likely assume the use of excitatory stimulation as applied by the contemporary art, Applicants submit that the present invention is not obvious in light of, among others, Gross, et al.

Second, combining the teachings of Gross, et al., with those of Schulman, et al., would not be obvious to one of ordinary skill in the art because so doing would destroy the purpose of the invention in Schulman, et al. A §103 rejection based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in the reference is improper. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). The Examiner has recognized that Schulman, et al., provide "a device that can be easily implanted into a patient through a hypodermic needle." Office Action mailed May 6, 2004, Paper #5, page 3; see also '540 patent, col. 1, lines 11-15 and col. 3, lines 55-57. Procedures implanting microstimulators using hypodermic needles are relatively minor, less invasive surgical procedures performed under a local anesthetic. By contrast, Gross, et al., teach a major surgical procedure under a general anesthetic of implanting an implantable pulse generator, which implantable pulse generators are traditionally much larger than the microstimulator of Schulman, et al. (i.e., "in the order of 2 mm in diameter", see '540 patent, col. 3, lines 53-54). Thus, it would be impossible, and would destroy the less invasive purpose of the invention disclosed by Schulman, et al., to implant the implantable pulse generator of Gross, et al., through a hypodermic needle as taught in Schulman, et al. Because the teachings of Gross, et al., would destroy the purpose of the invention of Schulman, et al., it would not have been obvious to one of ordinary skill in the art to combine the teachings of Gross, et al., with those of Schulman, et al.

Third, Schulman, et al., teach away from Gross, et al. "It is improper to combine references where the references teach away from their combination." See MPEP §2145 X.D.2; *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).

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Schulman, et al., state that the invention is a microstimulator to be implanted in the "immediate vicinity of tissue . . . desired to be stimulated". '540 patent, col. 1, lines 11-13. By contrast, the stimulator taught by Gross, et al., is not implanted in the immediate vicinity of the target (i.e., the sacral nerve) but is "implanted in the lower abdomen, and wired to nerves near the sacrum (the bone at the base of the spine)." '991 patent, col. 2, lines 37-39. Schulman, et al., teach away from the stimulator taught by Gross, et al., as a device that has "comprised a centrally-implanted stimulator package sending stimulation signals to . . . distant target sites." '540 patent, col. 1, lines 49-51. Thus, because Schulman, et al., teach away from the device disclosed by Gross, et al., it would not have been obvious to one of ordinary skill in the art to combine the teachings of Gross, et al., with those of Schulman, et al.

Fourth, even if Gross, et al. taught inhibitory stimulation as claimed, the Examiner is prohibited from using hindsight analysis to combine the teachings of Gross, et al., with at least Tanagho, et al., and Schulman, et al. An examiner may not perform a hindsight analysis and "use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention." *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 56 USPQ2d 1641 (Fed. Cir. 2000). In their response to the Office Action mailed September 12, 2003, Applicants argued that the prior art of record failed to teach inhibitory stimulation as claimed. In response, the Examiner added Gross, et al., attempting to use the Applicants' arguments and the claims as a blueprint fill the missing element of inhibitory stimulation with the teachings of Gross, et al. As established above, such hindsight analysis is prohibited.

For at least any one of the four reasons above, but especially because Gross, et al., fail to teach inhibitory stimulation as claimed, the teachings of Gross, et al., do not render the present invention obvious when combined with Tanagho, et al., Schulman, et al., (and Lin, et al.). Because Gross, et al., cannot be combined to render Claims 1, 3-11, 14-21, and 25-32 obvious, Applicants submit that such claims are currently in condition for allowance.

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In view of the above, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully Submitted,

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